Complete Summary

GUIDELINE TITLE

ASHP guidelines on preventing medication errors with antineoplastic agents.

BIBLIOGRAPHIC SOURCE(S)

American Society of Health-System Pharmacists. ASHP guidelines on preventing medication errors with antineoplastic agents. Am J Health Syst Pharm 2002 Sep 1;59(17):1648-68. [26 references] PubMed

COMPLETE SUMMARY CONTENT

SCOPE

METHODOLOGY - including Rating Scheme and Cost Analysis
RECOMMENDATIONS
EVIDENCE SUPPORTING THE RECOMMENDATIONS
BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS
QUALIFYING STATEMENTS
IMPLEMENTATION OF THE GUIDELINE

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IDENTIFYING INFORMATION AND AVAILABILITY

SCOPE

DISEASE/CONDITION(S)

Injury, sickness and health related to medication errors associated with antineoplastic therapy

GUIDELINE CATEGORY

Prevention

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Oncology
Pharmacology
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses
Health Care Providers
Health Plans
Hospitals
Managed Care Organizations
Nurses
Patients
Pharmacists
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

- To assist practitioners in improving their antineoplastic medication-use system and error-prevention programs
- To supplement the American Society of Health-System Pharmacists "Guidelines on Preventing Medication Errors in Hospitals" and address error prevention within diverse health care settings
- To provide updated general guidance to include a standard definition of a "medication error" and applicable aspects of recommendations from the National Coordinating Council on Medication Error Reporting and Prevention (NCCMERP)

TARGET POPULATION

Patients receiving antineoplastic therapy

NOTE: The setting for antineoplastic therapy is health care organizations, with an emphasis on hospitals and ambulatory care clinics that offer direct pharmacy services. The guidance may also be adopted by other settings, including physician office practices and home care.

INTERVENTIONS AND PRACTICES CONSIDERED

Medication Error-prevention Strategies

- 1. Educational and competency requirements for practitioners
- 2. Organized and up-to-date patient medical record and medication profile
- 3. Coordinated care among practitioners
- 4. Standardized medication ordering system:
 - Preprinted medication order forms
 - Computerized prescriber order entry system
 - Standardized format for medical order content including: dosage calculations, vocabulary and nomenclature, abbreviations, dosage limits and routes of administration
- 5. Standardized protocols for prescribing, preparation, dispensing, and administration of medication:
 - Medication-order verification system (9 checkpoint system)
 - Documentation such as checklists, worksheets to calculate dosages and administration rates, and treatment flow sheets
 - Standardized labeling and storage
 - Cross-checking
- 6. Manual or electronic medication monitoring

- 7. Patient and caregiver education
- 8. Quality assurance:
 - Periodic auditing of practitioner proficiency
 - Error reporting system
 - Analysis and resolution of medication errors
 - Periodic re-evaluation of medication use system

MAJOR OUTCOMES CONSIDERED

Not stated

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

American Society of Health-System Pharmacists staff provided drafters with results of a literature search from International Pharmaceutical Abstracts. Guideline developers obtained additional relevant references from MEDLINE (U.S. National Library of Medicine) searches and from personal files, and developed their expert opinions based on those references and the experiences of their own oncology facilities.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not applicable

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

In 1997, the Council on Professional Affairs of the American Society of Health-System Pharmacists (ASHP) launched development of a Practice Guideline on preventing errors in the use of antineoplastic medications to assist practitioners in improving their antineoplastic medication-use system and error-prevention programs. ASHP recruited oncology pharmacists from the National Institutes of Health Clinical Center and the National Cancer Institute to serve as drafters.

The first work product was an International Pharmaceutical Abstracts literature search. Drafters then developed an outline for the guidelines. Additional relevant references were identified and evaluated by drafters, based on the drafters' expert opinions and their extensive practice experience in their own institutions. Expanded drafts were created based on the outline. Content was refined and drafts were circulated for editing and review, both internal and external, and revised on the basis of those reviews.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The guideline was reviewed by the American Society of Clinical Oncology, the Oncology Nursing Society, the American Society of Health Systems Council on Professional Affairs and Board of Directors, and more than 20 practicing oncology pharmacists.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Comprehensive recommendations are provided in these guidelines for preventing errors with antineoplastic agents in health care organizations, with an emphasis on hospitals and ambulatory care clinics that offer direct pharmacy services. Nevertheless, it is strongly recommended that the guidance also be adopted by other settings, including physician office practices and home care. The

recommendations cover known procedural, technical, and behavioral elements that could systematically reduce a health care organization 's vulnerabilities to errors. However, strict adherence to good practice recommendations is not sufficient. Since the complexities of antineoplastic therapy afford unlimited opportunities for system failures, continuous diligence to verify accuracy is critical by all persons responsible for medication-use functions.

These guidelines focus on the medication-use responsibilities shared by and unique to specific professional health care disciplines, progressing from general to specific applications. The structure of the guidelines, by necessity, includes the repetition of some material, repeated and enhanced in specific sections and recommendations for different health care disciplines.

Recommendations for Health Care Organizations

Optimal and comprehensive patient care, especially for patients receiving antineoplastic agents, requires the participation of multiple health care disciplines. Systems are necessary to coordinate the functions throughout the medication-use process of prescribing, preparing, dispensing, and administering drugs, and to educate and counsel patients.

Health care organizations in which multiple disciplines are represented should establish committees with representatives from each discipline to develop policies and procedures for the medication-use process and to oversee its operation. These should include educational and competency requirements for persons with medication-use responsibilities, general system requirements that minimize vulnerabilities to errors, and periodic auditing of physicians, pharmacists, and nurses, proficiency with the system. Further, near misses and errors should be analyzed, and problems in the procedures that place patients and staff at risk should be resolved.

Education, Competency, and Credentialing. All practice settings should establish policies and procedures ensuring that health care providers who prescribe, prepare, dispense, and administer antineoplastic medications and monitor patients receiving those medications are competent to perform those functions. For pharmacists and nurses, specific education and experience or board certification in a practice specialty may be included in the credentialing process.

Employers should evaluate prospective employees ´ training and previous practice experiences for knowledge and mastery of the skills that are essential prerequisites for the new position. Prerequisites for employment should include discipline-appropriate training in how to safely handle antineoplastic drug products. Deficiencies in applicants ´ training and experience must be identified and remedied before new employees assume patient care responsibilities. Training for new and current employees should emphasize collaboration among health care providers to ensure optimal patient care and outcomes and worker safety.

All health care providers who prescribe, prepare, dispense, and administer antineoplastic medications and monitor patients receiving those medications should be oriented in their practice setting before commencing patient care responsibilities. Orientation should introduce to new employees all of the departments, service providers, and functions that affect patient care. Each

provider's roles and responsibilities should be identified, and it should be clarified how health care providers from different disciplines are expected to interact.

Further, health care organizations should require that all personnel who prescribe, prepare, dispense, administer, and handle hazardous drugs and materials that are contaminated with hazardous drugs and that all persons who may be exposed to hazardous-drug-contaminated materials during their job performance complete job-appropriate training and evaluation. They should demonstrate competence, knowledge, and proficiency in techniques and procedures for safely handling (preventing exposure to oneself, other persons, and the environment, and managing accidental exposure) hazardous drugs. Those competencies should be reassessed annually or more frequently if performance problems occur. It is the responsibility of medication-use system administrators and supervisory personnel to know the current government restrictions that limit or prohibit some health care providers from preparing and administering antineoplastic medications.

Health care providers who participate in an antineoplastic medication-use process and those who monitor patients receiving antineoplastics should be knowledgeable and have current information available about each of the following factors on the antineoplastic drug products used in their practice setting:

- 1. Names of antineoplastic drug formulations
- 2. Indications and whether those indications comply with the U.S Food and Drug Administration (FDA)-approved labeling or are part of an investigational protocol
- 3. Routes of administration
- 4. Administration schedules
- 5. Appropriate dosages and, when applicable, constraints for the maximum dose of medication that can be safely given during a single administration
- 6. Appropriate handling conditions
- 7. Potential adverse effects
- 8. Potential drug interactions

Every practice setting where cancer patients receive antineoplastic therapy should provide opportunities for continuing professional and technical education related to antineoplastic drug use. A portion of the annual continuing-education programs for health care providers specializing in oncology should be related to antineoplastic agents and their uses.

Providers who use drug-delivery devices, such as intravenous (i.v.) pumps and infusion controllers, to administer antineoplastic medications should be required to demonstrate competencies related to the clinical application, function (general use, operational limits, alarms), and care of these devices; problems that may occur with the devices; and troubleshooting.

Communication and Access to Information. Many errors occurring in the medication-use process are caused or promulgated by inadequate patient-specific information. Patients medical records should be organized and made readily accessible for use by all providers who prescribe, dispense, and administer antineoplastic medications to enable independent confirmation that all prerequisite criteria have been met before commencing antineoplastic treatment. In some cases, individual disciplines may keep additional patient records that

supplement the patient 's primary medical record. For example, it has historically been the responsibility of pharmacists and pharmacies to maintain patient-specific medication profiles, records of medications that were prescribed and dispensed for each patient.

Providers who practice at sites where pharmacists do not participate in patient care also should document and maintain medication profiles for their patients. Medication profiles for antineoplastic therapies should include at least the following information:

- 1. Patient's name and a unique identifying code or number
- 2. A brief medical history that identifies a patient's cancer diagnosis
- 3. Known drug-related adverse events, allergies, and medication-, nutrient-, and food-related sensitivities
- 4. Vital statistics that may affect treatment intensity, particularly those needed to calculate medication doses, including height, weight, body surface area (BSA), age, sex, and pertinent laboratory values (e.g., serum creatinine, creatinine clearance, liver transaminases)
- 5. Data about all medications used by a patient, including the date the medications were prescribed if it differs from the date they were prepared and administered, the date the medications were prepared and dispensed if it differs from the date the medications were administered, drug identity, drug dosage, total drug dosage administered per unit interval (e.g., day, week, treatment cycle), administration route, administration schedule as a function of the treatment plan (e.g., every three hours; days 1, 8, and 15), rate of administration (when relevant), prescribed duration of use (e.g., number of doses to administer; number of treatment hours, days, or weeks), and the product manufacturer 's identity and product lot numbers and expiration dates for drugs dispensed from that facility
- 6. Additional ingredients and diluting agents and the amounts used in extemporaneously compounded medications
- 7. Primary references that describe the treatment regimen
- 8. An up-to-date treatment history, including the treatment cycle or course number for each treatment repetition, the dates on which a patient last received treatment, how previous treatment was tolerated, and the cumulative amount of drug previously administered for medications with established absolute cumulative dosage limits (e.g., anthracyclines, bleomycin) or constraints against repeated administration as a function of time

Ambulatory care, home care, and managed care organizations are vulnerable to the same communication and interpretation errors that occur in hospitals. These settings and organizational arrangements, however, introduce additional opportunities for errors of omission and duplication when treatments and other services are provided at multiple locations and by more than one participating provider or group of providers. In hospitals and integrated health systems, patient-specific medical information has traditionally been communicated through a single comprehensive medical record. In contrast, providers in private practice, home care, and managed care organizations generally cannot rely on the availability of a comprehensive medical record, because medication prescribing, preparing, and administering may occur at geographically separate facilities.

Local policies should be developed to ensure that orders for a patient 's antineoplastic medications are transmitted accurately and completely, simultaneously protecting patient confidentiality. Electronic means of communication are recommended to transmit up-to-date, accurate, and comprehensive patient-specific medical information among providers. Thus, data entered into this electronic system by any one provider are immediately available to all. Until a single unifying network becomes available for all health care providers, portable printed and electronic records that ensure patient safety and confidentiality must be devised.

Schedule Coordination. Since oncology patients often receive care from more than one health care provider, their primary provider should coordinate patient care with other providers and facilities. Efficient organizational systems should have someone to coordinate a patient 's health care needs with the providers' schedules. Administrative coordinators are an interface between a patient 's primary provider and other providers and services. They plan and document scheduling for patients' treatments, laboratory tests, followup visits, consultations, supportive care, and assistance from home health care contractors, hospice facilities, and social services.

Standardize Medication Ordering. To the extent possible, medication prescribing, preparation, dispensing, and administration should be standardized. Patient care facilities should develop and use standardized preprinted medication-order forms or forms that are retrievable from a computerized database for requesting frequently used antineoplastic treatments and treatment-related services. Well-designed standardized medication-order forms decrease potential errors by organizing treatment information in a clear, consistent, and uniform format.

Standardized forms should be developed collaboratively with all local health care providers who prescribe, prepare, and administer antineoplastic medications. Forms should be preprinted with treatment-specific information, such as generic drug names, specifications for drug dosage and dosage modifications as a function of patient-specific variables, and administration routes and schedules. They should also include space for prescribers to note laboratory test results that affect dosages, administration rates, and treatment duration. These forms may also permit prescribers to schedule laboratory tests and request other services for comprehensive patient care.

Standardized medication-order forms simplify and expedite ordering medications by requiring prescribers to supply only patient-specific information, such as:

- 1. Patient's name and unique identifying code or number
- 2. Date the order was generated
- 3. Time and date treatments are to be administered
- 4. Patient-specific laboratory values (e.g., height, body weight, BSA, pertinent laboratory values) from which dosages and administration rates are calculated
- 5. Planned medication dosages and administration rates as a function of patientspecific factors and the calculated doses and rates to be administered
- 6. Patient's allergies and medication and nutrient sensitivities
- 7. Prescriber 's name and signature

8. Prescriber's telephone, pager, or fax number (or another means to communicate with the prescriber)

Preprinted forms should specify, by protocol number or publication reference, the treatment that is to be administered (Cohen et al., 1996; Kohler et al., 1998).

For investigational antineoplastic treatments, standardized forms should also include the study name and protocol number. Color-coded forms, for example, may be used to designate different types of treatment, such as commercially marketed antineoplastic and investigational medications.

Standardized order forms eliminate many of the problems related to misinterpreting medication orders that are commonly associated with nonstandardized orders; however, health care providers must be aware that interpretation errors may still result from illegible handwriting. Multipurpose preprinted forms that list antineoplastic medications alphabetically may also contribute to prescribing errors when two similar drug names appear in close proximity. Since lined paper can obscure the details of a prescriber´s orders, preprinted forms should be printed on unlined paper.

Self-replicating forms (e.g., carbon copies, no-carbon-required paper) can produce copies that are difficult to read. Providers who prepare and administer medications on the basis of a copy of a prescriber 's order should be wary of ambiguous notations, artifact markings, and omissions on the copy. Each facility should restrict antineoplastic ordering (e.g., access to medication-order forms) to providers with the appropriate clinical privileges. Health care organizations that depend on standardized forms must also ensure that only the most current versions of standardized forms are available and that obsolete forms are recalled and destroyed.

Computerized Prescriber Order Entry. Computerized prescriber order-entry (CPOE) systems provide many of the same safety and convenience features as preprinted order forms with several important advantages, including an efficient means for simultaneously disseminating orders to various providers. CPOE simplifies prescribing and eliminates the potential for introducing errors into a medication-use system when intermediaries are required to accurately interpret and transcribe orders into a manual database.

CPOE can also provide online information about drug dosages and administration schedules, both of which can be updated from a central location. Computer software can also provide additional safety and convenience features, such as automated scheduling of multiple-day treatments, repeated treatment cycles, and laboratory tests and automated calculation of mathematically derived patient-specific data (e.g., BSA, lean body weight, drug dosages). In addition, software can decrease the likelihood of errors by incorporating features that detect drug dosages and administration schedules greater than and less than predetermined limits and by alerting system users when potentially interacting medications are prescribed (Berard et al., 1996).

Safeguards are also required for CPOE systems. Access privileges should be limited to authorized health care providers. The system should electronically

record when users enter, change, and discontinue orders. Providers should review and verify orders before treatment is started.

Oral Orders for Antineoplastic Medications. Except for discontinuing treatment, medication-use systems should not permit health care providers to transmit or accept orders to commence or modify antineoplastic medication that are communicated orally (Cohen et al., 1996; Attilio, 1996; Kloth, 1997). Oral orders for medications, spoken face-to-face or by telephone, circumvent an essential checkpoint in the order-verification process, whether they are communicated directly to persons who prepare medications or received and reported by one or more intermediaries (Fischer et al., 1996).

Stat Orders for Antineoplastic Medications. It is rarely necessary to begin antineoplastic treatment as quickly as possible. In general, Stat orders for antineoplastic medications potentially compromise essential order-verification safeguards and are almost never appropriate. Except for urgently required treatments, antineoplastic medication preparation and administration should be scheduled when staffing is adequate to ensure that appropriate safety checks are performed and to implement treatment. It is essential that patient care is not compromised under any circumstances. Persons who design medication-use systems are challenged to incorporate antineoplastic medication-order-verification systems that cannot be circumvented and do not introduce unnecessary delays in processing the orders.

Standardize Dosage Calculation. Medication-use systems should establish whether drug dosages should be routinely calculated as a function of actual or ideal (lean) body weight and develop standardized criteria that direct dosage calculation as a function of this weight. Treatment plans and medication orders should indicate whether patients actual or ideal body weight was used in calculating drug dosages and identify the equation from which dosages were calculated.

Methods should be standardized for calculating BSA and ideal body weight, rounding calculated results (e.g., drug dosages and administration rates), and changing dosages and administration rates in response to changes in patients weight and stature. For dosage and administration rates calculated from pharmacokinetic data, the mathematical equations that describe how calculated values were derived should appear in the treatment plans and medication orders.

Standardize Medication Orders. Standards should be established for the content of an acceptable medication order, requirements for patient-specific measurements, and data that must be included on medication-order forms (Lajeunesse, 1997; Attilio, 1997). The following standards are recommended:

- 1. All orders for patient care services should be clearly dated
- 2. When ordering antineoplastic medications, the generic drug name should be used; use generic drug names approved by the United States Adopted Names (USAN) program. Brand names are not acceptable unless they aid in identifying combination drug products or a particular drug formulation (e.g., to distinguish between liposomal and nonliposomal product formulations)
- 3. Specify the dosage form

- 4. Orders for medications should include the patient-specific data from which drug doses are calculated (height, weight, BSA, laboratory test results). When drug dosages and schedules are modified for current or anticipated pathologies, treatment plans and medication orders should explicitly identify the factors on which treatment modifications are based
- 5. Drug dosages and calculated doses should be expressed in metric notation whenever possible. The word units should never be abbreviated in medication orders where drug dosages and administration rates are expressed in biological activity units (e.g., aldesleukin, asparaginase, bleomycin)
- 6. Medication orders should specify the drug dosage, calculated dose, and append the total cycle or course dosage
- 7. Administration vehicle solutions and volumes should be specified, unless standard solutions and volumes have been established
- 8. Specify the administration route
- 9. Specify the administration rate
- 10. Specify the administration schedule and the duration of treatment. Treatment plans and medication orders should specify the interval between repeated doses, the days on which each dose is to be given within a treatment cycle or course, and the total length of a treatment cycle or course
- 11. Specify the dates and times when drug administration is to commence, or identify the temporal sequence in which each medication is to be administered. When 1200 is written as 12 a.m. or 12 p.m., it may be incorrectly interpreted. Directions indicating events for 1200 should be written as 12:00 noon, or 12:00 midnight, or expressed in the 24-hour system

A medication order that complies with these recommendations would appear as follows for a patient with a BSA of 2 m^2 : Azorhubarb injection 100 $mg/m^2/dose = 200 mg$ in 100 mL 5% dextrose injection/dose, administer by continuous intravenous infusion over 24 hours, every 48 hours for three doses days 1, 3, and 5. Start at 8:00 a.m. on April 1, 2001 (total dose/cycle = 600 mg).

Although health care providers have traditionally used abbreviations, acronyms, and nicknames to describe antineoplastic medications and treatment regimens (e.g., ADR [doxorubicin], MTX [methotrexate], VBL [vinblastine], "platinum" [carboplatin or cisplatin], ICE [ifosfamide, carboplatin, and etoposide], MOPP [mechlorethamine, vincristine, procarbazine, and prednisone], ProMACE [prednisone, methotrexate, doxorubicin, cyclophosphamide, and epipodophyllotoxicin], and Cy-TBI [cyclophosphamide and total body irradiation]), the practice is potentially dangerous and should be avoided. Abbreviations for drug names, scheduling information, and directions for medication use should be prohibited in medication orders. Nonstandard abbreviations, Latin abbreviations, and apothecaries weights and measures should not be used in orders for antineoplastic medications. Whenever possible, measurement units should be expressed in metric notation.

Establish Dosage Limits and Acceptable Routes of Administration. Medication-use systems should include utilization limits for antineoplastic medications. Constraints should be developed to limit maximum antineoplastic drug dosages and administration routes and schedules. Multidisciplinary peer review should be completed before established drug administration limits are exceeded (Cohen et al., 1996; Attilio, 1996). These constraints should include the maximum amount of an antineoplastic drug that may be administered as a single

dose, the maximum amount that may be administered during a defined time interval (including maximum administration rates for parenterally administered medications), and the routes by which each drug should be administered.

Constraints for dosage and administration rate may be defined by treatment regimens and protocols and may vary among protocols. In contrast, the types of treatments administered in some practice settings may be consistently similar, permitting the establishment of absolute maximum dose limits within that practice setting.

Limits should also be established for the maximum amount of an antineoplastic drug that may be administered during one treatment course or cycle and, when appropriate, the maximum amount of drug that may be administered to a single patient within his or her lifetime (Cohen et al., 1996). In addition, dosage limits should be established for antineoplastic medications used in specific combination regimens (defined for each drug) in which clinical toxicities may be exacerbated by combining agents with overlapping adverse-effect profiles.

Antineoplastic drug-use limits should appear prominently in printed treatment descriptions (e.g., protocol summaries, "care maps," schematic treatment diagrams) and on printed medication-order forms and computer-based medication- order templates. Computer software that alerts health care providers whenever an order for antineoplastic medications exceeds defined limits would be ideal. For patients who receive antineoplastic medications for which cumulative dosage limits have been established, cumulative dosage data should be constantly updated in their permanent medical records and in any supplementary records. Patients´ cumulative dosage data should be audited and independently confirmed by health care providers when verifying orders for antineoplastic medications (Cohen et al., 1996; United Kingdom Joint Council for Clinical Oncology [UKJCCO], 1994).

In each health care organization, the medication-use system should include a multidisciplinary committee that oversees matters related to medication-use limits. The committee should proactively develop and establish policies and procedures for resolving disagreements related to patient treatment among providers; whether medications should be prepared, dispensed, and administered if a discrepancy cannot be resolved; and how medication-use-related disputes are to be resolved. Committee membership should comprise all providers who have responsibilities in the medication-use process in the organization (Cohen et al., 1996).

Investigational Antineoplastic Medications. Cancer patients often receive investigational (i.e., experimental) anticancer treatments at facilities participating in clinical trials. Consideration must be given to ensure that the same safety precautions and checks that are used for FDA-approved antineoplastic therapies apply similarly to prescribing, preparing, dispensing, and administering investigational medications and monitoring patients who receive those therapies.

Facility administrators should ensure that adequate staff is maintained to support an investigational drug program (Fischer et al., 1996). Ideally, nurses and pharmacists should be involved early in the process of developing clinical protocols involving the use of commercially marketed and investigational

antineoplastic medications (Cohen, 1997). This helps to ensure that investigational medications are prepared and administered in accordance with local policies and procedures. Nurses and pharmacists should be voting members on regulatory and review committees that evaluate the scientific and ethical treatment of patients receiving antineoplastic medications and monitor investigational therapies (e.g., institutional review boards) (Cohen et al., 1996).

Because a protocol governs and supplies the rules for drug use in clinical trials, an up-to-date copy of the study protocol should be available for review at all sites where medications are prepared and administered. All staff should be informed through inservice education programs before new protocols are implemented. Inservice programs and study-related information should be provided by persons associated with the investigational study (e.g., principal investigator, associate investigators, protocol chairperson, study-coordinating personnel). If an investigational protocol is to be conducted at more than one site within a health care system, procedures should be developed to ensure that up-to-date information is available at all study sites where patients receive protocol-directed care.

Procedures for supplying health care providers with information about patients´ dose assignments, drug dosage, and schedule modifications should also be devised. A separate procedure should be established allowing independent dose-checking activity among all disciplines involved in the medication-use process for investigational drugs.

Recommendations for Multidisciplinary Monitoring of Medication Use and Verification

Independent medication-order verification is an essential safeguard that ensures the accuracy and appropriateness of medical treatment. It is imperative that health care providers resolve any questions related to medication orders before treatment commences. Providers should recognize that medication- order verification and other system safeguards ensure patients safety (Cohen et al., 1996; Kohler et al., 1998; UKJCCO, 1994).

Lack of information about patients and their medications has been described as the most frequent cause of medication errors (Kloth, 1997; Leape et al., 1995). In order to independently verify prescribers´ orders for medications, all persons who prepare and administer antineoplastic medications and those who monitor patients who have received antineoplastics should also have access to complete, up-to-date copies of treatment protocols and patient-specific data (Cohen et al., 1996; Kloth, 1997; UKJCCO, 1994). Drug information and reference materials should be readily available to all persons who provide patient care.

Each health care provider has a responsibility to share information with other providers and consultants to ensure patient safety and an optimal treatment outcome. Policies that regulate treatment verification standards should describe how prescribers, medically responsible and senior authorizing physicians, pharmacists and pharmacy technicians, persons responsible for administering medications, and other persons who are responsible for transcribing and transmitting medication orders should interact.

Providers who prescribe, prepare, dispense, and administer antineoplastic medications should perform as many independent manual checks as possible. Treatment-verification systems may incorporate computerized medication-order safety checks but should also include as many independent manual checks as possible (Cohen et al., 1996; Fischer et al., 1996). Ideally, computerized systems are used to calculate and verify dosages and the rate and route of administration for antineoplastic drug orders and to screen medication orders for compliance with dosage limits. In addition to facilitating chemotherapy-order processing, computer software can also serve as a double check on prescribers´ orders. Systems requiring pharmacists to transcribe prescribers´ medication orders into a computerized or manual drug-ordering system should have a second pharmacist recheck all order-processing documents and product labeling before a drug product is dispensed.

Providing medications to patients includes four discreet steps: prescribing, preparation, dispensing, and administration. The ideal verification system has nine established checkpoints to ensure that an antineoplastic drug is accurately prescribed, prepared, dispensed, and administered to the patient for whom it was intended (See Figure 1 in the original guideline document). Different individuals should complete each check so that no single person bears responsibility for checking his or her own work.

Prescribing antineoplastic medications (checkpoint 1). Health care providers who prescribe, prepare, and administer antineoplastic drugs should be familiar with the entire treatment regimen. A prescriber should complete as many orders as possible comprising a patient 's antineoplastic treatment regimen and include orders for preparative and supportive care medications. This practice ensures that orders can be checked for completeness and accuracy and compliance with planned treatment.

When orders for antineoplastic drugs must be countersigned by a second medically responsible individual, the person who countersigns the medication orders should critically evaluate each order for an antineoplastic treatment. This is checkpoint 1. The orders should be compared with patient-specific data and verified against original reference sources that describe the treatment regimen (e.g., a published article, validated standard reference text, investigational protocol).

Preparing antineoplastic medications (checkpoints 2–4). Checkpoint 2 requires persons receiving a prescriber´s order for antineoplastic medications to review the original written medication orders and independently verify them against published standards (e.g., product package labeling, reports published in professional journals, treatment protocols, standard reference textbooks).

Because erroneous information sometimes appears in published information, orders for noninvestigational antineoplastic medications should be verified against the primary reference in which the specific treatment was described (e.g., published reports, study protocols, meeting proceedings). If a primary reference is not available, the treatment regimen should be confirmed with a resource that previously had been validated as accurately describing the planned treatment (locally compiled handbooks, guides, and compendia) or at least two alternative publications, including reviews and reference textbooks (Cohen et al., 1996;

Attilio, 1997). Investigational drug doses and administration schedules must be verified against a study protocol that was approved by all relevant regulatory agencies and study sponsors (e.g., institutional review board, National Cancer Institute, FDA).

Although preprinted order forms preclude the necessity of repeatedly verifying drug names, dosages, routes, and schedules each time a preprinted form is used, all medication orders should be evaluated for completeness, compliance with the planned regimen, and, during repeated courses, deviations from previous treatments by following these requirements:

- 1. Measurements from which a patient's medication dosage and administration rate are calculated should be confirmed (e.g., height, weight, BSA)
- 2. The date a patient was last treated and the next planned treatment date should be compared to ensure that an appropriate interval has elapsed since treatment was last administered
- 3. Patient-specific data (e.g., height, weight, BSA) should be remeasured and, when applicable, recalculated to determine whether changes from previous measurements indicate corresponding changes in dosage or administration rates
- 4. Appropriate laboratory test and physical assessment values should be evaluated, and primary treatment references should be consulted to determine whether they are within acceptable ranges or if treatment modifications are indicated
- 5. A patient 's allergy, drug sensitivity, and adverse drug effect histories and his or her current medication profile should be evaluated for potential drug interactions with planned antineoplastic treatment

Orders prescribed by physicians-in-training and non-physician health care providers with prescribing privileges (e.g., nurse practitioners, physician assistants) should be verified with at least one medically responsible person, other than the prescriber, who is knowledgeable about medical oncology. Verification includes confirming correct treatment before commencing the initial cycle, dosage and administration schedule modifications, and deviations from planned or expected treatment.

For patients who receive treatment in clinical studies in which more than one primary or ancillary treatments are prescribed (e.g., dose- and duration-escalating studies), treatment assignment and dosage and administration schedule modifications should be confirmed with at least one person directly associated with the clinical trial, other than the prescriber (e.g., the principal investigator, an associate investigator, research nurses or pharmacists, a study coordinator or chairperson). Consult with the prescriber when expected treatment modifications were not ordered or when nonstandard modifications were prescribed.

Instructions for diluents, drug administration sequence and duration, number of doses, and starting date and time should be checked. Review and confirm that appropriate ancillary and supportive medications that facilitate antineoplastic drug delivery and those required by protocol have been prescribed and are complete and accurate (e.g., premedications, hydration, cytoprotectant and "rescue" medications, antiemetics, hematopoietic growth factors). Discrepancies between

prescribed medications and planned treatment should be brought to the prescriber's attention and resolved before medication preparation proceeds.

At checkpoint 3, after treatment orders have been verified, all work related to medication-order processing and preparation accuracy should be routinely documented in a standardized format. Drug preparation work sheets (sometimes referred to as work cards or admixture or compounding logs, sheets, and cards) identify the drug products prepared for each patient and the persons who prepared and checked the medications. Although layout and design may vary among work sheets, and data may be organized as a continuous log in which each drug product appears on separate consecutive lines or as a separate record for each patient, all work sheets should detail the techniques used in preparing the drug products. They should also identify special preparation and dispensing information, such as the indication of special product containers, requirements for filtration, the need for special diluents, intermediate dilution steps, and how and when administration sets should be attached to the drug product container. Order processing, drug preparation, and processing records should be confirmed by a second individual (preferably a pharmacist) (Cohen et al., 1996; Attilio, 1996). The calculations written on preparation work sheets should be independently verified by a second health care provider who did not prepare the work sheet. Independent verification should include checking the work sheet for completeness and accuracy of content, with particular attention given to special preparation instructions. A checklist identifying the necessary elements in a drug preparation work sheet may be helpful for this step (See Figure 2 in original guideline document) (Cohen et al., 1996).

At checkpoint 4, drug products should be checked, after preparation, against both the preparation work sheet and the original order by an individual who was not involved in preparing the work sheet. Checklists may also be helpful for this step (Cohen et al., 1996).

Dispensing antineoplastic medications (checkpoint 5). Checkpoint 5 requires persons dispensing medications to patients or caregivers for outpatient use to verify a patient 's identity when a medication is dispensed. Patients who self-administer their medications or personal caregivers should visually examine the medication, confirm whether its appearance meets their expectations, and compare its instructions with information they received from their health care providers (e.g., a chemotherapy calendar).

Dispensing and administering antineoplastic medications (checkpoints 6–9). At checkpoint 6, before starting treatment, each antineoplastic medication should be checked against the prescriber´s orders by at least two individuals who are trained and competent to administer antineoplastic medications. All dosage- and administration rate-related calculations should be independently confirmed. Health care providers should routinely confirm that the medication will be administered to the intended patient by comparing a patient´s name and unique identifying code or number with medication labels (e.g., alpha–numeric characters or bar codes) and that a drug product´s identity, ancillary components (e.g., additional medications, diluent, and vehicle solutions), route of administration, and schedule are correct.

At checkpoint 7, health care providers should examine the medication container and note whether the content's general appearance is what was expected. Many chemotherapeutic parenteral products have distinctive colors, and product coloration should be confirmed before administration.

At checkpoint 8, patients who self-administer their medications (or receive it from personal caregivers) should carefully read the container 's label to confirm the product 's identity and review its instructions for use each time they take a medication.

At checkpoint 9, patients should be encouraged to ask questions about their treatment before its administration and compare its appearance and medication label with information they received about the treatment.

In ambulatory care practice, it is common for patients to receive parenteral antineoplastic medications in a setting where a physician and a nurse complete all tasks related to prescribing, preparing, administering, and monitoring treatment without a pharmacist´s participation. Under these circumstances, the two health care providers involved should check the other´s work. Both providers should be involved in the entire process. The person preparing antineoplastic medications should work from written orders.

Recommendations for Prescribing Systems and Prescribers

Antineoplastic prescribing is complicated by numerous medical publications that report indications, dosages, and administration schedules inconsistent with FDA-approved product labeling. Antineoplastic treatments are frequently based on preliminary reports, meta-analyses, and promising, albeit anecdotal, information. Prescribers must exercise great care in correctly interpreting this information and clearly communicating orders for antineoplastic medications with other health care providers.

System administrators should weigh the merits of requiring orders for all antineoplastic medications and other high-risk drugs prescribed by physicians-intraining to be countersigned by a senior physician with expertise in the specialty to safeguard against errors in interpretation and prescribing.

Health care providers with privileges of prescribing antineoplastic drugs should complete an orientation of local policies and procedures related to prescribing antineoplastics before they are permitted to order them for patient care.

Health care providers should locally develop standardized dosage and administration schedule modifications for each antineoplastic medication. Treatment modifications may be appropriate for patients with the following characteristics: (1) preexisting pathologies and whose health may be compromised by treatment with particular antineoplastics (e.g., withholding or decreasing bleomycin dosages in patients with preexisting pulmonary dysfunction or cardiotoxic agents in patients with congestive heart failure), (2) a history of severe, prolonged, or cumulative adverse effects after previous antineoplastic treatments, (3) impaired physiological function that predisposes patients to altered pharmacodynamic responses (e.g., renal or hepatic impairment), and (4) low or decreased performance status.

Health care providers should also establish standardized guidelines for prescribing drugs that are routinely administered concomitantly with antineoplastic medications. Medication-use guidelines for supportive care and ancillary agents (e.g., antiemetics, hydration, chemoprotectants) should be made accessible to all health care providers who prescribe, prepare, and administer antineoplastic drugs and for persons who perform clinical monitoring.

When generating medication orders in a setting where preprinted ordering forms, CPOE, and other electronic and mechanical means (e.g., a typewriter) are not available, prescribers should legibly print the names of medications, dosages, routes of administration, and administration schedules in plain block letters and Arabic numerals. Unless it is considered inappropriate by the prescriber, handwritten medication orders should include the indications for which they are prescribed (e.g., for sore mouth, for nausea, for chronic lymphocytic leukemia).

When antineoplastic treatment (ordering, preparing, and administering) is coordinated at a single location, it is the prescriber´s responsibility, or in the conduct of clinical trials, it is the principal investigator´s responsibility, to provide information about the treatment (e.g., protocols, publication reprints) to those who prepare and administer medications and monitor patient outcomes. It remains the prescriber´s responsibility to answer questions and provide information to other health care providers when treatment is implemented in a place that is geographically separate from the prescriber´s location. Prescribers, clinical investigators, and medically responsible staff are strongly urged to provide to healthcare providers who prepare and administer antineoplastic medications a complete printed (or electronically reproduced) copy of the treatment regimen.

General Guidelines for Prescribing Antineoplastic Medications (Cohen et al., 1996; Beckwith & Tyler, 2000 Part 1; Kohler et al., 1998; United States Pharmacopeial Quality Review, 1997). The following are general guidelines for prescribing antineoplastic drugs:

- 1. Instructions for medication regimens should be explicit, complete, clear, and easy to follow. Treatment regimens should be described accurately and consistently in all written and published materials in which antineoplastic medication use is described
- 2. Medication-use systems should require health care providers to use standardized vocabulary and nomenclature for describing treatment with antineoplastic medications
- 3. Use uniform and consistent notations to express quantifiable amounts (dosage, concentration, volume, and time)
- 4. Never trail a whole number with a decimal point followed by a zero (e.g., write "5 mg," not "5.0 mg")
- 5. When writing amounts less than one, the expression should be written with a leading zero, which precedes the decimal point (e.g., "0.125 mg)
- 6. In all treatment plans and medication orders, identify the dosage, the calculated dose, and, parenthetically, the total dosage (the amount of drug as a function of body weight, BSA, or other factors) that patients are to receive during a treatment cycle
- 7. When treatment day enumeration is arbitrary, day 1 typically describes the day treatment commences. In contrast, hematopoietic progenitor-cell transplantation regimens often include day 0, and significant treatment-

related events both before and after a progenitor-cell graft is administered are distinguished by negative (minus) and positive (plus) prefixes, respectively

Specific Recommendations for Parenterally Administered Medications (Kohler et al., 1998). Health care providers should adhere to the following guidelines for parenteral antineoplastic drugs:

- 1. In treatment plans and orders, doses should be expressed as the total amount of medication to be administered from a single container (i.e., the total amount of medication per syringe, bag, or other container)
- 2. For medication admixtures that can be prepared in more than one way, practitioners should institute a priori, standard, and consistent methods directing how each medication will be prepared and administered
- 3. For drug products with extended stability and when a medication is administered from a single container for more than 24 hours, a prescriber´s order for treatment should specify the amount of medication to be administered during each 24-hour interval (Kohler et al., 1998). A drug order for a patient with a BSA of 2 m² should read: "Drug XYZ" (8 mg/m²/day × 3 days) 48 mg in 150 mL 0.9% sodium chloride injection by continuous intravenous infusion over 72 hours, days 1–3. Start on 04/01/2001 at 0800 (total dose/cycle = 48 mg)

Specific Recommendations for Orally Administered Medications (Kohler et al., 1998). Health care providers should adhere to the following guidelines when oral medications are the prescribed antineoplastic treatment:

- 1. In treatment plans and medication orders, describe drug doses and schedules as the amount of medication to be taken per dose, not as a total daily dose that is to be taken in divided doses
- 2. In treatment plans, medication orders, and instructions to a patient, identify the number of doses to be administered or taken
- 3. When doses for a solid orally administered dosage form are greater or less than available dose strengths, specify whether and how doses are to be rounded to the nearest capsule or tablet strength (e.g., Should tablet formulations be broken to deliver a calculated dose? Should high and low doses be administered on alternating days to deliver an average dose?)
- 4. Whenever possible, include instructions about how medications are to be taken with respect to food ingestion and whether particular types of food may affect medication activity
- 5. Explicitly identify essential ancillary medications and supportive care that should accompany an antineoplastic treatment regimen.

Recommendations for Medication Preparation and Dispensing Systems and Roles for Pharmacists

For each practice setting, persons representing the various health care disciplines that prescribe, prepare, and administer antineoplastic medications should participate in planning and managing local medication-use systems.

Standardize Medication Preparation Guidelines. Health care providers should establish standardized guidelines for reconstituting, diluting, admixing, packaging,

and labeling commonly used antineoplastics and other medications that are routinely administered with antineoplastics. Each practice facility should also establish a standardized method for labeling multidose vials and reconstituted drug products. Standardized medication preparation guidelines should be prominently displayed (e.g., as a chart) for easy accessibility in areas where orders are processed and medications prepared.

Policies and procedures should be developed for situations in which medications are prepared at facilities that are geographically removed from where treatment is administered. Procedural protocols should describe requirements for medication packaging, storage conditions during transportation, duration of transport, and handling after delivery. Medication couriers should receive training in organizational policies for handling medications and should immediately report when conditions and handling practices deviate from procedural standards. In addition, handling procedures should ensure patient confidentiality and provide quidelines for emergency situations, such as hazardous-drug spills.

Persons who prepare and dispense antineoplastic medications should ensure timely drug delivery to patients and patient care areas after receiving written orders. If dispensing is delayed for any reason, health care providers awaiting the medications should be notified (Cohen et al., 1996).

Quality Assurance. In collaboration with health care providers who prescribe and administer medications, pharmacists and persons who prepare and dispense medications should take the initiative in developing and managing quality assurance programs for their medication-use systems. These programs should preeminently include surveillance and reporting systems that track potential and actual medication errors and evaluate the proximal causes of errors among processes and systems and preventive measures (Cohen et al., 1996; "Top priority actions," 1996). The major advantage of multidisciplinary participation is that each discipline's perspectives and methods for conceptualizing system flaws and solutions can be incorporated in designing strategies for preventing medication errors. Confidential reporting is essential to the success of a medication error surveillance and reporting system. Only by understanding what causes and contributes to errors can the number of errors be reduced. In designing a medication-error surveillance and reporting system, strategic emphasis should be placed on understanding why errors occur and not on blaming or censuring personnel (Pepper, 1995).

Orientation on Medication-Error Reduction. Pharmacy supervisors and managers should develop an orientation program about medication errors commonly associated with antineoplastic drugs to train pharmacy personnel who prepare and dispense antineoplastic medications. Pharmacists should develop ongoing interdisciplinary educational programs that focus awareness on potential medication errors with antineoplastic medications, strategies for preventing errors, and local and national medication-error reporting and evaluation systems for all practitioners who have direct patient contact.

Pharmacists should engage the support of medical and nursing administrators and supervisors to encourage their staff (particularly those in professional training programs) to complete antineoplastic medication-error awareness programs (Kloth, 1997). Educational programs should be discipline specific. Program content

should include medication-error case scenarios and discussion about the effects that medication errors have on patients 'quality of life and the health system (Cohen et al., 1996; Fischer et al., 1996).

Standardize Drug Procurement and Storage. Pharmacists who select and procure drugs should strive to minimize or eliminate look-alike drug product containers and limit the availability of different vial sizes for parenteral medications whenever possible (Attilio, 1996). Frequent additions to the variety of available drug products and changes among alternative manufacturers drug products can contribute to medication-use errors and should be avoided. When practicable, drug products with similar names and packaging should not be stored next to each other. Medication-use systems that involve a formulary should separate nonformulary products from those that are on the formulary. Health care providers should familiarize themselves with antineoplastic drugs that are not on their formulary before prescribing, preparing, and administering them.

Standardize Medication Preparation and Dispensing. Antineoplastic medications should be dispensed in ready-to-administer dosage forms whenever possible. Generally, antineoplastics for intermittent parenteral administration should be prepared so that each medication container has only one dose. The risk of incorrect medication use is increased when the amount of drug dispensed in a single container exceeds the amount to be administered during a 24-hour period. It is essential that individuals and committees responsible for developing and overseeing medication-use systems establish guidelines on whether prescribers may order antineoplastic preparations to be administered from a single container for more than 24 hours. In all practices where parenteral drugs with extended stability (more than 24 hours) are sanctioned, it is imperative that the duration of their use is clearly labeled and that health care providers are trained to correctly prescribe, prepare, and administer them (Kohler et al., 1998).

When preparing an antineoplastic admixture, a quantity of medication that most closely approximates the prescribed dose should be segregated from other drug supplies. For treatment regimens that include two or more drugs, especially when medications are to be administered by different routes, the medications should be physically segregated during preparation and when administered. Compounded medications should be prepared one at a time, using standardized techniques whenever possible. When measuring diluent solutions used to reconstitute medications and drugs to be added to a secondary container, a person other than the individual who measured the volume should visually confirm the measurement before the solutions are transferred from the measuring device to the secondary container. This may be accomplished by visual inspection or by weighing syringes, other transfer devices, and intermediate product containers before fluid transfer is completed. Alternatively, post hoc methods for checking medication preparation include "pulling back" syringe plungers and marking syringe barrels to demonstrate the volume of fluid that was injected into the secondary container. In any medication-checking system, the person who confirms the technical accuracy of the person who prepares the admixture should examine all containers used during preparation.

Antineoplastic agents are administered parenterally by many routes other than the intravenous route (e.g., intrathecally, intrahepatically, intrapleurally, intraarterially). Inadvertent administration by the wrong route (e.g., giving

vincristine intrathecally) can result in serious or fatal consequences. Medicationuse systems should include policies and procedures that distinguish medications administered by the intravenous route from those intended for administration by other routes.

Standardize Medication Labeling. Strict procedures should be established for standardizing medication labeling. A uniform, systematic labeling method should be used, especially when multiple drugs are prepared for a single patient. Medication labels should be mechanically printed (not handwritten). Extemporaneously compounded antineoplastic medications should be labeled immediately after preparation. Oral medications should also be sealed with childproof or poisoning-prevention closures. Auxiliary labels may facilitate distinguishing among medications that are administered by particular delivery methods.

Labels for oral dosage forms, rectal suppositories, and topically applied unit-dose products should include all of the following information:

- 1. Patient's name and unique identifying code or number and patient's location within a treatment facility (when applicable)
- 2. Date (with or without specifying time) the medication was dispensed
- 3. Generic drug name
- 4. Dosage form and strength
- 5. Amount of medication per dose (when the container dispensed holds more than one dose)
- 6. Administration route
- 7. Detailed instructions to the patient for self-administering the medication
- 8. Supplemental administration instructions, such as the starting and completion dates and times, number of doses to administer, cautionary information about when medications are to be taken in relation to food ingestion and other medications, and instructions and warnings regarding administration route, storage conditions, and container closures
- 9. The number of drug product units dispensed within each container (the number of tablets, capsules, or suppositories, packaged in a single container)

Labels for injectable dosage form containers should include all of the following information:

- 1. Patient's name and unique identifying code or number and patient's location within a treatment facility (when applicable)
- 2. Generic drug name
- 3. The amount of medication per container and the amount of medication per dose when a product container holds more than one dose, as drug product containers may hold more medication than is intended for a single administration (e.g., multiple doses for intermittent administration). Identify how much overfill is added to a container when excess medication and fluid volumes are added to displace air from the tubing lumen ("dead space") in administration sets
- 4. Route of administration; for example, medications prescribed for administration other than by the intravenous route—especially those for intrathecal administration—should bear ancillary labels that distinctively identify the intended administration route

- 5. The name and either the amount or concentration of all drug additives in a drug product
- 6. Diluent (vehicle fluid) name
- 7. The volume of fluid to be administered. Volume to be administered should be specified, especially when it differs from the total volume within a medication container (i.e., when the product contains an amount of fluid in excess of the volume to be delivered)
- 8. Administration rate and duration. Ideally, both administration rate and duration should be specified. Because administration rates can be calculated from the volume to be administered and duration of administration, duration is the essential component
- 9. Supplemental administration instructions, such as starting and completion dates and times, prohibitions about when medications are not to be administered in relation to other medications, instructions and warnings regarding administration route, handling, and storage conditions (e.g., information about special requirements for administration sets including inline filtration, warnings to avoid intrathecal administration with vinca alkaloid drugs, and hazardous-drug warning labels)
- 10. When it is necessary to prepare more than one medication intended for sequential administration, the container labels should be numbered. Indicate the sequence in which each container is to be used plus the total number of containers (e.g., bag 1 of 3, bottle 3 of 7)
- 11. Date (with or without specifying time) the medication was ordered or prepared. Investigational compounds, in particular, should be labeled with the date and time they were prepared
- 12. Date (with or without specifying time) after which a medication should no longer be used (expiration information)
- 13. Cautionary warnings as required for hazardous-drug products (Occupational Safety and Health Administration (OSHA) Training & Education Directive, 1.15, 1995)
- 14. Storage specifications
- 15. The name (with or without specifying location or telephone number) of the institution, pharmacy, or practice from which a medication was dispensed and the prescriber's identity.

Credentialing Pharmacists for Antineoplastic Medication-Use Programs. Pharmacy managers and supervisors should require pharmacist employees to complete training and demonstrate competencies related to antineoplastic medication use, evaluating medication orders, preparing antineoplastic medications, safe handling procedures, error surveillance and reporting programs, and local policies as a prerequisite to pharmacist credentialing. Health care organizations should periodically reassess pharmacist employees ´ competencies related to their responsibilities, increasing the frequency of reassessment if performance problems occur (Beckwith & Tyler, 2000 Part 2).

Roles for Pharmacists. Among primary health care providers, pharmacists generally are best positioned to ensure that medications are used rationally and safely and increase others ´ awareness about medication errors and how to prevent them. Pharmacists should participate in all aspects of patient care related to antineoplastic treatment, including developing rational policies for safe and appropriate medication use and other services consistent with pharmaceutical care (Cohen et al., 1996; Kloth, 1997). Pharmacists should participate with other

primary health care providers in multidisciplinary groups that develop, implement, and periodically reevaluate practice-specific procedures and processes for verifying antineoplastic medication orders, resolving procedural questions related to confirming and processing medication orders, and evaluating and resolving disputes among health care providers.

Each organization should establish a minimum acceptable level of pharmacist participation in the error-prevention elements of patient care, such as proactively reviewing medication orders, screening laboratory results, providing drug information and patient counseling, and reviewing drug storage conditions (Cohen et al., 1996; Waddell et al., 1998).

The following areas are recommended for pharmacist participation:

- 1. Educate health care providers about medication errors
- 2. Independently verify medication dosages, routes of administration, and schedules
- 3. Participate in multidisciplinary efforts to establish drug-specific utilization constraints that limit maximum doses, administration rates, and administration schedules for antineoplastic medications
- 4. Participate in multidisciplinary efforts to standardize the prescribing vocabulary
- 5. Participate in multidisciplinary efforts to educate patients, their families, and personal caregivers
- 6. Improve communication among health care providers and among health care providers, patients, and caregivers
- 7. Work with drug manufacturers

Drug information resources and education for providers. Pharmacists should help ensure the availability of up-to-date references on the appropriate use of antineoplastic drugs for all health care providers involved in medication use (Cohen et al., 1996; Fischer et al., 1996). Drug information resources should provide information about drug products FDA-approved labeling and investigational uses. Information should be developed or selected, including drug-specific precautionary warnings and information about adverse effects, particularly dosage- and schedule-limiting effects; potential interactions with other drugs, disease states, and foods; administration methods, including drug admixture stability and compatibility data; usual adult and pediatric dosages; dosage recommendations for single- and multiple-treatment courses; treatment modifications for persons with concurrent pathologies or end-organ impairment; and pharmacokinetically based dosing and monitoring guidelines.

Pharmacists should develop and provide discipline-specific educational materials about antineoplastic medication use to health care providers who prescribe, prepare, and administer antineoplastic medications. The instructional tools developed for each professional health care discipline should complement the materials developed for the other disciplines (Cohen et al., 1996). Whenever new antineoplastics, treatment regimens, and treatment protocols are introduced into their practice setting, pharmacists should assume a continuous, proactive leadership role in developing educational programs and materials for health care providers, patients, and caregivers (Cohen et al., 1996; Fischer et al., 1996).

For patients whose care is transferred from oncologists to nonspecialist practitioners, oncology pharmacy specialists should develop and provide drug monographs, medication- use summaries, and other treatment-related materials describing how antineoplastic medications and treatment regimens are to be accomplished (Attilio, 1996; Kloth, 1997). The need is especially acute among organizations and practitioners who provide local care for patients enrolled in clinical trials or receiving investigational antineoplastic treatments.

Treatment protocols. Oncology pharmacy specialists should participate in developing treatment protocols for standard treatments and clinical investigations. In practice settings where antineoplastic agents and treatment regimens are used routinely, pharmacists should initiate the development of tools that standardize the way medications are ordered, thereby facilitating accurate and appropriate prescribing, order interpretation and verification, and medication processing and dispensing (Fischer et al., 1996; Thorn et al., 1989). Pharmacists should lead initiatives to standardize drug preparation procedures, including reconstitution, dilution, and drug admixture methods for commonly used parenteral antineoplastic medications (Attilio, 1996).

CPOE. When circumstances and resources permit, pharmacists should work with information systems personnel, computer programmers, and software vendors to develop CPOE systems. System requirements should include mechanisms for standardizing medication orders, decreasing opportunities for error by minimizing data entry, and screening orders for medication doses and administration schedules that exceed established limits. Pharmacists should advocate for and participate in establishing maximum safe antineoplastic dosage and scheduling limits with physicians, nurses, and other primary health care providers.

Vocabulary and nomenclature. Pharmacists are uniquely qualified to lead multidisciplinary efforts toward developing and implementing clear, detailed, standardized vocabulary and nomenclature for antineoplastic treatment regimens, medication orders, and administration instructions. Pharmacists should participate in the early stages of protocol development for standard treatments and clinical investigations to ensure that pharmacotherapeutic regimens are clearly described, easily understood, and incorporate standardized language, content, abbreviations, and units of measure (Cohen et al., 1996; Kohler et al., 1998; Kloth, 1997).

Patient education and counseling. When meeting or interviewing patients, their family members, or other home-based caregivers (e.g., completing medication-use and allergy histories, screening blood pressure, performing ongoing treatment response assessment, dispensing medications), pharmacists should provide medication education and counseling. They should verify that patients and their caregivers understand the following:

- 1. The purpose of the medication and its intended use
- 2. The appropriate use and safe handling of medications and administration devices
- 3. Appropriate temperature and safe storage conditions
- 4. Special precautions to prevent exposure to hazardous materials that may be present in patients´ clothing, linens, body fluids, and excreta during and after treatment
- 5. The potential interactions with other medications and foods

- 6. Common and possible adverse effects associated with the medication
- 7. Methods for preventing and managing adverse effects
- 8. What to do if potentially serious adverse effects occur (Cohen et al., 1996; Hutcherson & Gammon, 1997)

Pharmacists should provide educational materials to patients and suggest supplemental and alternative information resources, such as the National Cancer Institute information services department (1-800-4-CANCER or 1-800-422- 6237 and www.nci.nih.gov), the American Cancer Society, libraries, and bookstores (Cohen et al., 1996).

Advocates for patients rights. Pharmacists should encourage patients and their caregivers to participate in their own care and advise patients how to protect themselves from medication errors. Pharmacists should advise patients that they are entitled to satisfactory answers from their health care providers. Pharmacists should encourage patients to double-check the details of their treatment, including drug names and dosages, and to request dosage recalculation if their biological measurements change. Pharmacists who participate in developing treatment plans and protocols should ensure that consent-for-treatment forms truly secure patients informed consent. Pharmacists should help to prepare treatment consent forms; provide patients with an accurate and detailed description of their treatment plan in clear, unambiguous, and easily understood language and answers to their questions about the treatment and alternative treatment options; and assess patients understanding of expected and possible outcomes. Pharmacists should also describe their role as primary care providers and the care they provide (Cohen et al., 1996; Attilio, 1996).

Clinical intervention, analysis, and performance improvement. In addition to dispensing medications, pharmacists in various settings can provide a vital service toward improving the quality of patient care by implementing a proactive clinical intervention program and documenting health care providers deviations from planned antineoplastic treatments. Longitudinal data collection, analysis, and reporting can reveal system flaws that failed to prevent or facilitated prescribing errors, suggest targets for quality improvement, and validate pharmacists interventions.

Pharmacists should proactively work with other primary care providers to establish medication-use reporting and surveillance programs. Committees established for this purpose should comprise representatives from medical, nursing, pharmacy, and risk-management disciplines. Programs should continually evaluate local medication-use systems to identify potential problems and solutions related to medication use and prevent medication errors (Cohen et al., 1996; "Top priority actions," 1996). Such programs in institutions should seek endorsement from appropriate local multidisciplinary committees (e.g., pharmacy and therapeutics, medical executive, and clinical practice committees).

Feedback for pharmaceutical manufacturers and regulators. Pharmacists should work with pharmaceutical manufacturers and FDA to eliminate ambiguous, confusing, and potentially misleading drug product and treatment information from published resources (e.g., product packaging, package inserts, official compendia, and promotional information). Pharmacists working in the pharmaceutical manufacturing industry should proactively identify preventable

causes of product-user errors and adverse effects associated with product labeling, packaging, and promotion (Lesar, Lomaestro & Pohl, 1997). Pharmacists´ voluntary participation in national reporting programs can increase the awareness of medication errors and promote error prevention throughout the nation´s health care system. These aggregate data promote changes in product identity, packaging, labeling, commercial information, and marketing practices that are subject to manufacturers´ control and governmental regulation (Cohen et al., 1996; USP Quality Review, 1997).

Recommendations for Medication Administration Systems and Roles for Nurses

Nurses are often the last link in the chain of health care providers who provide treatment with antineoplastic medications. To safeguard patients from mistakes that have potentially lethal consequences, elaborate systems have evolved that include:

- Requirements for credentialing persons who administer antineoplastic medications
- Tools and methods to facilitate documentation and identification of correct medication use
- Independent verification of medication orders
- · Accurate documentation of medication use and effects and patient care
- Strict compliance with regulations and practice standards
- Patient education regarding medication safety

Credentialing Nurses for Antineoplastic Medication-Use Programs. Nursing managers and supervisors should require nurse employees to complete training and demonstrate nursing care-related competencies, such as administering antineoplastic medications, caring for patients who have received antineoplastic medications, and knowing about local policies. Specialty certification is encouraged. Nurses may be required to complete additional training and competency assessments before they are permitted to administer experimental medications. Training usually combines didactic and supervised practical instruction. Didactic instruction generally includes training about specific antineoplastic agents, appropriate dosages and dosage ranges, adverse effects and clinical toxicities, administration techniques, and safe handling. Technical experience in administering antineoplastic medications commonly starts with roleplaying exercises and practicing technical skills on nonhuman models and proceeds through clinical interactions under the supervision of an experienced mentor. Performance evaluations test trainees for satisfactory cognitive and motor competencies. Health care organizations should periodically (annually or more frequently if performance problems occur) reassess nurses competencies related to their responsibilities.

Standardized Tools for Recording Medication Administration. Nurses with a variety of experiences have devised and contributed to designing tools to facilitate the prevention of drug administration errors, such as standardized work sheets used to calculate medication dosages and administration rates and checklists of pertinent laboratory results and physiological measurements. Treatment flow sheets provide easily interpretable information about when a patient 's previous treatments were administered, whether dosages and medication delivery deviated

from planned treatment, and the cumulative amount of medication administered. Thoughtfully designed treatment flow sheets may become part of a patient 's permanent medical record and can be an invaluable resource for patient care.

Checking Orders and Equipment for Administering Antineoplastic Medications. Medication orders for antineoplastics are commonly checked by two nurses working independently. As has been discussed previously, double checks by two licensed health care providers help to ensure that medications are prescribed and administered appropriately. In addition, nurses should evaluate and confirm the functional integrity of vascular access devices (and devices for other administration routes), medication pumps, and other devices that control medication delivery. For adjustable and programmable mechanical and electronic devices, mechanical adjustments or electronic programming for delivering the correct dose at the appropriate rate should be verified with another health care provider who is knowledgeable about the delivery device before it is used to administer medications. Another individual who checks adjustments and programming should independently examine the adjustments made to the device and review the programming.

Recording and Tracking Antineoplastic Use. After medications have been administered, it is a nurse 's responsibility to manually or electronically record the activity. The documentation should include the patient 's name, the names of all medications administered, dosages, administration routes, rates of administration, the date and time administration began, the duration of administration or time that treatment was completed, and whether adverse effects were observed or reported by the patient during or after administration. Communications with patients, other health care providers, and personal caregivers should be documented in an objective, chronological narrative style, reporting the dates and times the events occurred, the names of involved persons, and how questions and problems were resolved.

Nurses and other personnel should immediately report to medically responsible personnel and their supervisors any instance in which medications were used incorrectly and the events attributable to the error. In response to discovering a medication-use error, a provider´s primary responsibility is to ensure the patient´s safety. Subsequently, the error and related circumstances should be recorded as is indicated by specific policies and procedures. Medication-use error reports (also called occurrence or incident reports) should be written in an objective, chronological, narrative style without editorial remarks and speculative comments. Comprehensive incident reports are useful in discovering and evaluating system flaws and may provide the impetus for improving medication-use systems.

To prevent medication errors, nurses and other personnel who administer antineoplastic medications must comply with policies and procedures that define standards of practice. It is important, however, to periodically reevaluate practice standards in order to assess how well a medication-use system functions, make appropriate changes, and, ultimately, improve patient safety and the quality of care.

Health care providers administering antineoplastic medications should not deviate from previously stated guidelines for ordering, preparing, and administering

antineoplastic agents. Examples of inappropriate practice include borrowing medications from a patient 's drug supply to give to another patient and preparing agents without the proper facilities or staff. Medication administration schedules should be followed as closely as possible; providers and caregivers should strive to comply with treatment plans. Drug administration should be documented promptly after it is completed, and providers administering antineoplastic medications should rigorously comply with local requirements for documenting treatment. To prevent the inadvertent duplication of treatment, it is recommended that one individual assumes the primary responsibility for each patient during a work period (shift or tour of duty).

Nurses and Patient Education. Nurses and other personnel who administer antineoplastic medications should encourage patients and their personal caregivers to ask questions about their treatment. Patient education guidelines may be included in treatment maps and clinical care plans.

Recommendations for Patient Education

Well-informed patients (and their authorized caregivers) are the vital last link in the safety chain to prevent errors related to antineoplastic medications. Patients are entitled to know all pertinent facts about the medications they receive during their treatment. Health care providers have an obligation to encourage patients to ask questions and to provide answers. The following suggestions are offered to help patients and their caregivers ensure optimal outcomes from the cancer therapy medications.

Multifocal Medication Education. Patients need multifocal education about the purpose, adverse effects, schedules, routes of administration, and descriptions (e.g., colors, shapes) for all the medications they will receive during their treatment. This includes the primary antineoplastic regimen and all ancillary and supportive medications, such as anti-emetics and medications that hasten bone marrow recovery. When patients are well informed and the information they receive is reinforced by nurses, pharmacists, and other caregivers, they are better prepared to detect a misinterpreted medication order and assertively question conflicting information (Cohen, 1995). Health care professionals should be sensitive to the emotional aspects of patients with cancer when planning medication education. Education should take place at a time when a patient is able to listen and understand. Medication education should not be attempted when patients are sedated or confused as a result of medications or immediately after receiving their cancer diagnosis.

Patients should participate in their care by asking questions about their cancer treatment and related medications and by confirming the regimen with their nurse before receiving treatment. Health care providers should make educational materials available in counseling and treatment areas to encourage patients to learn more about their cancer therapies.

Health-System Procedures Education. Patients should understand the health system's plan for antineoplastic medication-error prevention. They should become familiar with their providers' routine procedures for checking medication orders so that they can understand the safeguards that have been established and why delays may occur before their treatment can be started. For example,

patients can remind the person administering chemotherapy to compare medication labels with a patient's identity and can verify their height and weight each time they are measured.

Patient Participation in a Medication-Use System. Patients (or their caregivers) should be knowledgeable about their medications and the ways in which the medications are to be administered according to their treatment plan. In some circumstances, patients should be encouraged to take responsibility for some of their care to help improve their quality of life. Examples include self-administering medications, maintaining the patency of vascular access devices, giving themselves a subcutaneous injection, and troubleshooting a problem with the portable infusion pump. Patients should demonstrate their abilities to perform these functions if they are included in the therapy plan.

Patients should be given a detailed treatment calendar that identifies all of the medication events that are expected to occur throughout their treatment. Patients should be encouraged to keep their calendar with them to compare the expected treatment with what is being dispensed and administered.

Patients´ Responsibilities. Patients should be taught to detect and to seek help in managing adverse effects that may occur during their cancer treatment. Patients should promptly inform their health care providers about adverse effects experienced during a chemotherapy cycle before the next cycle commences. Patients should keep a list of the medications that they self-administered to treat these adverse effects.

It is important for health care providers to be able to determine a potential for interactions between a patient 's nonantineoplastic medications and the chemotherapy they are to receive. Therefore, patients should provide to their providers a list of all medications they are using, including over-the-counter preparations, natural products and dietary supplements, and other complementary and alternative medicines.

Recommendations for Manufacturers and Regulatory Agencies

Pharmaceutical manufacturers have a responsibility to exercise care in designing product packaging and labeling and in promoting their products, as these features may contribute to errors in prescription, product selection, preparation, and administration. Companies that market antineoplastic agents should develop and support educational programs that encourage safe and accurate prescribing, preparation, administration, and handling of their products. The following guidelines address some of the major areas.

Product Naming, Packaging, and Labeling. Companies should avoid trademarking drug names that look or sound similar to those of other drug products. Proprietary drug names for new products and product formulations should be dissimilar from other generic and proprietary names. Manufacturers should avoid appending letters and numbers to drug names as this practice can result in potential confusion with dosage strengths, medication quantities, and the amount of medication to be administered.

Product packaging and labeling should provide clear, easily distinguished features to identify a drug and the amount of drug per dosage unit (e.g., tablet, capsule, wafer) and within a product container (e.g., vials, bags, bottles, prefilled syringes). It is particularly important that a drug product 's USAN-approved generic name appear more prominently than other information on the product label. Drug names should be printed on both the front and back of the containers and packaging of parenteral drugs; "TALL man" characters should be used to distinguish between similar drug names. Container labels for drugs that are in solution and for those that require reconstitution or dilution before they are used should identify the total drug content in mass units (or biological activity units) rather than concentration (Cohen, 1995). Product packaging and labeling that include both mass and concentration values should be designed to display mass units more prominently.

Labels should be unique and well designed. Distinguishing colors and contrasting hues facilitate identifying and distinguishing drug products and products in different strengths and concentrations. Warnings and special or unique instructions should be prominently displayed on product packaging and labeling. Unique labeling and packaging techniques should be used to prevent product misidentification and to warn about dosing errors and unique characteristics that predispose medication users to potentially serious or life-threatening toxicities. Examples include the unique way that the Platinol-AQ brand of cisplatin injection (Bristol-Myers Squibb, Princeton, NJ) is packaged to prevent misidentification with carboplatin and the cautionary statements on vials containing vincristine sulfate injection that warn against using the entire contents of a vial for a single patient (on bulk packages) and that intrathecal administration may be fatal.

A statement that declares a drug´s approved routes of administration is optional and may or may not appear on product packaging. If the agent is approved for administration by only one route, it must be clearly indicated.

Appropriate storage temperatures or conditions should be clearly visible on drug labeling and packaging.

Drug labeling and packaging must identify the manufacturer's product lot or control number.

Drugs that must be reconstituted and diluted before clinical use should include reconstitution instructions that identify appropriate diluents and volumes.

A manufacturer's drug product preparation date (for experimental drugs) or an expiration date should be clearly visible on the product label.

Special instructions, such as "Shake Well," "Do Not Shake," "Albumin Required," and instructions for dilution, should appear on product labeling. In cases where important information will not fit on a product label, a package insert may be required as part of the labeling and packaging.

Product changes should be widely communicated to prescribers, pharmacists, nurses, and other health care providers involved in drug prescribing, preparation, and administration.

Package inserts and product information that describe medical indications, medication doses, administration schedules, and product use should not include abbreviations. This is especially important for drugs used in complex treatment regimens.

Educational Materials and Programs. Pharmaceutical manufacturers and drug product sponsors should be encouraged to provide educational materials and programs that promote and encourage safe use of their drug products. Programs should clearly explain the indications appearing on FDA-approved labeling, dosages, methods for preparation, and administration routes and schedules. Treatment descriptions should be standardized and consistent with guidelines designed to prevent medication-use errors (Kohler et al., 1998). Medication names and administration information should not be abbreviated in educational and promotional materials.

Regulatory Oversight. Regulatory agencies have a responsibility to review product packaging, labeling, and advertising to ensure that their content accurately reflects safety and efficacy data and conforms with language that has been approved by the FDA. A key component in those reviews should be that the product packaging and labeling facilitate safe and appropriate use and prevent users from making errors in selecting, preparing, and administering a drug product. Pharmacists should be consulted in screening proprietary drug names, product packaging, and labeling before drug products are approved for commercial use.

Managing Medication Errors

Medication-use errors with antineoplastics are distinguished from errors with other types of drugs in two important ways, both of which relate to antineoplastics? inherent toxicity. Individually and categorically, the therapeutic index for antineoplastic drugs is less than that for any other class of drugs. Adverse effects are an expected pharmacodynamic consequence attendant with antineoplastic use, and clinical toxicities may occur and persist at substantially lower dosages and schedules than are therapeutically used. The second characteristic distinguishing between antineoplastics and other types of drugs is that with the latter, subtherapeutic doses may not produce adverse effects that delay retreatment. In contrast, antineoplastic medications given in error at subtherapeutic doses (or underdoses) may not provide a therapeutic benefit, but they may compromise patients 'ultimate response to therapy by delaying effective treatment until adverse effects are resolved. Underdoses may also cause or contribute to cumulative long-term patient harm as a result of adverse effects, delayed treatment, or both. It should be noted that antineoplastic treatments are almost always repeated, and the effect of a medication-use error may not be apparent until long after the error occurred. Consequently, if treatment plans and medication orders are not verified during each treatment cycle, errors may be compounded during repeated cycles and go undetected throughout an entire treatment course.

In addition to the actions already set forth in the "American Society of Health-System Pharmacists (ASHP) Guidelines on Preventing Medication Errors in Hospitals," the following are recommended after detecting a medication error (Beckwith & Tyler, 2000 Part 2):

- 1. Implement monitoring and interventions for controlling injurious effects and ensuring patient safety
- 2. Determine if an error could have previously occurred during prior treatment in the same patient and in other patients. Medication preparation work sheets or logs and drug administration records should be evaluated. Unexpected toxicities and an apparent or unaccountable lack of therapeutic and adverse effects should be investigated when it is suspected that a medication error occurred
- 3. Seek the advice of health care professionals from various disciplines. The perspective of providers in other disciplines may facilitate discovering and understanding the circumstances that allowed a medication error to occur
- 4. Determine whether an immediate temporizing or "stopgap" change in policy or procedure is necessary to prevent recurrence of an error while the proximal cause is being analyzed
- 5. Provide immediate professional counseling and support for employees implicated in causing or contributing to an error resulting in serious patient harm. Counseling and support should be offered to all personnel who learn that they have been involved in a medication error without regard for how recently the error occurred
- 6. Establish procedures to inform and follow up with patients and their families about a medication error
- 7. Understand that reporting medication errors and adverse drug reactions is a responsibility that should be shared by all health care providers. However, health systems may designate a person or committee specifically responsible for reporting and investigating medication errors and adverse drug reactions. In investigational drug studies, a study's principal investigator must report serious adverse events to the trial's sponsors (the drug manufacturer and the investigational new drug application holder) and to the institutional review board that oversees study conduct. Investigational drug sponsors are required to report to the FDA serious adverse effects associated with investigational agents, even if they are caused by a medication-use error
- 8. Encourage practitioners to report medication errors to a national medicationerror tracking program. This allows other providers to learn how medication errors occur and how they can be prevented. Reporting mechanisms for medication-use systems should be standardized by policy. Mechanisms must be developed for ongoing, interdisciplinary analysis and use of information that is reported to medication-error databases.

Categorizing Medication Errors. In practice settings where a variety of disciplines provide patient care, serious potential and actual errors should be reported to an oversight committee composed of representatives of all the disciplines that provide care. By standardizing the way medication errors are reported, comparisons between reports and databases are facilitated, error trends are more easily identified, and system- based solutions can be developed. Continuous oversight by a multidisciplinary quality-assurance committee promotes continuity and permits all primary patient care providers to evaluate system flaws and develop and improve the quality of processes and systems that safeguard patient care. Medication-use oversight committees are advised to review medication-error reports from systems other than their own and evaluate their local medication-use system for design characteristics that may permit similar errors (Kloth, 1997; Cohen, 1997).

"ASHP Guidelines on Preventing Medication Errors in Hospitals" recommend adopting a system for categorizing medication-error severity such as the one developed by Myers, 1995 and Hartwig, Denger & Schneider, 1991. Although this system is generally applicable to errors of occurrence with antineoplastic drugs, it categorizes errors by severity and prioritizes them without consideration for the frequency at which repeated errors occur. Accordingly, errors with the highest severity ranking receive the greatest efforts toward remediation. In contrast, potential errors are assigned a "zero" ranking, the lowest severity level, as they do not reach patients. By relegating potential errors to the lowest priority category, this outcome severity-based system risks trivializing system-design flaws. Errors discovered before they reach patients could cause devastating consequences, yet serious nascent errors are often transformed into potential errors only by serendipitous discovery. Therefore, potential errors should be distinguished from errors of occurrence and subcategorized based on their potential to cause harm (Myers, 1995; Hartwig, Denger & Schneider, 1991). However, potential errors should not be taken less seriously than errors of occurrence. When serious potential errors are discovered, the systems and processes that contributed to the errors should be evaluated and their proximal causes identified. The greatest efforts toward remediation of potential errors and errors of occurrence should be concentrated on eliminating the causes of errors that could have and had, respectively, the greatest adverse effects on patients \(\) health.

NCCMERP's definition for medication errors includes any event that may cause or lead to inappropriate medication use (National Coordinating Council on Medication Error Reporting and Prevention, accessed 2001). The definition is complemented by the NCCMERP Taxonomy of Medication Errors, a comprehensive expandable tool intended for use in developing databases and analyzing medication-error reports. The Taxonomy provides standardized language and structure for recording and tracking medication-error-related data for errors of occurrence and potential errors. NCCMERP permits interested persons to adopt it as it is presented or adapt it for use in a particular practice setting.

CLINICAL ALGORITHM(S)

A clinical algorithm "Medication-order Verification System" is provided in the original guideline document.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

REFERENCES SUPPORTING THE RECOMMENDATIONS

References open in a new window

TYPE OF EVI DENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Prevention of medication errors associated with antineoplastic therapy
- Improved medication error-prevention programs in health care settings
- Improved patient safety and quality of life

POTENTIAL HARMS

Not stated

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

Because of the complexity of and differences in practice settings and organizational arrangements, aspects of these guidelines may be more applicable to some practice settings than others. Pharmacists, physicians, nurses, and other health care providers should use their professional judgment in assessing and adapting the guidance to their own setting. These guidelines address a specific aspect of the medication-use process and should be augmented as appropriate by other American Society of Health-System Pharmacists practice statements and guidelines.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness
Safety

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

American Society of Health-System Pharmacists. ASHP guidelines on preventing medication errors with antineoplastic agents. Am J Health Syst Pharm 2002 Sep 1;59(17):1648-68. [26 references] PubMed

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Not applicable: The guideline was not adapted from another source

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the American Society of Health-System Pharmacists (ASHP) Web site.

Print copies: Available from the American Society of Health-System Pharmacists, 7272 Wisconsin Avenue, Bethesda, MD 20814.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

• ASHP guidelines on preventing medication errors in hospitals. Am J Hosp Pharm. 1993 Feb; 50(2): 305-14.

Electronic copies: Available in Portable Document Format (PDF) from the <u>American Society of Health-System Pharmacists (ASHP) Web site</u>.

Print copies: Available from the American Society of Health-System Pharmacists, 7272 Wisconsin Avenue, Bethesda, MD 20814.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on December 3, 2003. This summary was verified by the guideline developer on December 30, 2003.

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